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REMARKS

In view of the following remarks, the Examiner is requested to allow claims 1, 2, 6-11, 18-23, 26 and 31-43, the only claims pending and under examination in this application.

Claim 36 has been amended to include the limitation that penetration of the cement into the cancellous bone stops substantially simultaneously with cessation of said vibration. This amendment is fully supported by the specification and claims as originally filed. For instance, see page 5, lines 5 to 7. Accordingly, this amendment adds no new matter and its entry is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claim 39 has been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner alleges that the limitation of "4 to 10 cubic centimeters" is new matter. The Applicants respectfully disagree.

The Applicants would like to draw the Examiner's attention to page 15, lines 13 to 15, where it is stated:

"On average, about four to five cubic-centimeters of cement can be injected on each side, and it is known to inject up to about eight to ten cubic-centimeters per side."

Accordingly, in view of the above disclosure of the specification, the Applicants contend that the limitation "4 to 10 cubic centimeters" is fully supported by the

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specification and is not new matter. Therefore, the Applicants respectfully request the 35 U.S.C. § 112, first paragraph, rejection of Claim 39 be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 1-2, 7-9, 11, and 31-33, 36-38, 40-41 and 43 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Constantz *et al.* (USPN 6,149,655).

Before turning to the merits of this rejection, the Applicants wish to point out that the present invention represents a significant contribution to the art. Prior to the Applicant's work in this area, calcium phosphate cements such as Norian's calcium phosphate cement were not FDA approved for use in vertebral compression fractures. The reason for this lack of approval was that the high pressures typically employed for the delivery of Norian SRS into a tightly confined spaces with ready venous or arterial access, such as compressed vertebral bodies, had an unknown potential for emboli formation, which formation could lead to serious side effects including death of the patient. In discovering that vibration can be employed to achieve highly controlled delivery of calcium phosphate cements to target locations such as vertebral bodies without substantial pressure, the Applicants have overcome this danger of emboli formation. Accordingly, the present invention represents a significant contribution to the art and a significant benefit to patients.

Turning now to the merits of the rejection, according to the MPEP, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. See MPEP 2131.

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An element of both Claims 1 and 11 is that the penetration of the cement into the bone stops substantially simultaneously with the cessation of vibration. Claims 2, 7-9 and 31-33 depend from either Claims 1 or 11 and therefore incorporate all the limitations recited therein.

As explained in the Applicants' previous response, Constantz does not teach the delivery of orthopedic cement by the use of vibration in a controlled manner such that when the vibration stops the penetration of the cement stops substantially simultaneously with the cessation of vibration.

In an attempt to rebut this position, the Examiner continues to assert that because Constantz discloses that vibration may be utilized to enhance infiltration of the cement, Constantz teaches that when vibration is stopped infiltration is also "substantially stopped."

However, the Applicants contend that the Examiner's conclusion is unfounded and not supported by the teachings of Constantz. Nowhere does Constantz teach that penetration of the cement stops substantially simultaneously with cessation of vibration. As the Examiner points out, the use of vibration in Constantz is to enhance infiltration of the cement. As defined by the Merriam-Webster Online Dictionary the word "enhance" means to "heighten" or "increase."

While addition of a given force may heighten or increase a given action, it does not necessarily follow that removal of the force would stop the action from occurring. For example, if one pushes on a slowly slipping car on the edge of a cliff, the rate at which the car goes over the cliff may be enhanced. However, removal of the pushing force will not stop the car from going over the cliff-the car will continue to go over the cliff. As such, while the pushing force may enhance or speed up the rate at which the car goes over the cliff, removal of the force does not stop the car from going over the cliff.

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All that Constantz teaches is that vibration enhances. This does not mean that when vibration is stopped that infiltration is stopped. The cement, like the car, will continue pursuant to the teaching of Constantz, to infiltrate the porous bone.

Therefore, the Examiner's conclusion is not supported by the teachings of Constantz. Contrary to the Examiner's conclusion, Constantz does not teach that the penetration of the cement into the bone stops substantially simultaneously with the cessation of vibration.

In view of the above, the Applicants contend that Constantz fails to teach every limitation of Claims 1-2, 7-9, 11 and 31-33 and therefore respectfully request that the rejection of Claims 1-2, 7-9, 11 and 31-33 under 35 U.S.C. § 102(b) over Constantz be withdrawn.

Claims 36-38, 40-41 and 43 have also been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Constantz *et al.* (USPN 6,149,655).

Independent Claim 36 has been amended to include the limitation that the penetration of the cement into the bone stops substantially simultaneously with the cessation of vibration. Claims 37, 38, 40 – 41, and 43 depend from Claim 36 and incorporate all the limitations recited therein.

As stated above, Constantz does not teach the delivery of orthopedic cement by the use of vibration in a controlled manner such that when the vibration stops the penetration of the cement stops substantially simultaneously with the cessation of vibration. Constantz, therefore does not teach every limitation of Claims 36-38, 40-41 and 43 and therefore fails to anticipate the claimed invention. The Applicants, therefore, respectfully request the § 102(b) rejection be withdrawn.

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Claim Rejections – 35 U.S.C. § 102/103

Claim 10 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Constantz *et al.* or, in the alternative, under 35 U.S.C. 103(a) as allegedly being obvious over Constantz *et al.*

According to the MPEP § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Claim 10 ultimately depends from Claim 1 and adds the limitation that the delivery device includes a vibratory element for vibrating a delivery needle. As previously stated, Claim 1 includes the limitation that the penetration of the cement into the bone stops substantially simultaneously with the cessation of vibration. Constantz neither teaches nor suggests that the penetration of the orthopedic cement into the bone stops substantially simultaneously with the cessation of vibration. The reason that Constantz does not suggest this element is because Constantz *et al.* is completely silent as to whether penetration would cease at substantially the same time as removal of vibration. Accordingly, Constantz does not acknowledge the benefit of controlling vibration in such a way that when the vibration ceases so does penetration.

Therefore, because Constantz does not teach every element of the claimed invention it cannot be used to anticipate Claim 10. Furthermore, because Constantz fails to at least suggest every element of the invention Constantz fails to render Claim 10 obvious. In view of this, the Applicants respectfully request the §§102(b)/103 rejection of Claim 10 be withdrawn.

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Claim Rejections – 35 U.S.C. § 103

Claim 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* in view of Sproul (USPN 6,832,988).

Claim 6 depends from Claim 1 and additionally includes the step of aspirating marrow from the cancellous bone. As previously stated, Claim 1 includes the limitation that the penetration of the cement into the bone stops substantially simultaneously with the cessation of vibration. As reviewed above, Constantz neither teaches nor suggests that the penetration of the cement into the bone stops substantially simultaneously with the cessation of vibration. As Sproul is recited solely for its disclosure of aspiration during vertebroplasty it fails to cure the defect of Constantz. In view of this, the combination of Constantz and Sproul fail to teach or suggests every element of Claim 6 and the Applicants respectfully request the § 103(a) rejection of Claim 6 be withdrawn.

Claims 18-21, 23, and 26 have been rejected over 35 U.S.C. § 103(a) as allegedly being unpatentable over Saito (USPN 6,340,299) in view of Smith *et al.* (USPN 4,653,957).

Claims 18, 23 and 26 are directed to a system, a device, and a kit (respectively) for delivering orthopedic cement to a target bone site. An element of the claims is a pneumatic vibratory element.

Saito is directed to a dental cement mixing and pouring device for delivering a dental cement composition to a target site, i.e., a mold or a tooth. The Examiner admits that Saito is deficient in that it fails to disclose a pneumatic vibratory element. The Examiner therefore relies on Smith to remedy this deficiency. Smith, however, is directed to a device for the mixing and pouring of cement that is used in construction.

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A *prima facie* case of obviousness cannot be established because these references constitute non-analogous art and cannot be combined in the manner suggested by the Office action. The MPEP § 2141.01 (a) I states that in order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of the Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.

The field of the Applicants' endeavor is the delivery of orthopedic cements. See page 1, line 7. The particular problem with which the Applicants are concerned is the controlled delivery of orthopedic cement to a target bone site without the substantial application of pressure. Smith, however, is directed to a device to be used in the production and finishing of concrete. Concrete is an aggregate of cement, sand, gravel and rock that is typically used in construction for the formation of pavements, building structures, foundations, roads, and the like. Additionally, Smith is directed to using an instrument that delivers both pressurized air and vibration in amount sufficient to work gravel into a finished surface. See the abstract of the invention.

Accordingly, Smith is not directed to the controlled delivery of orthopedic cement to a target bone site without the substantial application of pressure. Therefore, Smith represents non-analogous art because it is neither in the Applicant's field of endeavor nor is it reasonably pertinent to the problem with which the Applicant was concerned. Accordingly, one of reasonable skill in the art would not look to Smith for guidance as to the delivery of orthopedic cement to a target bone cite without the use of substantial pressure because Smith is concerned with the production and finishing of concrete for use in industrial applications. As such, the Applicants contend that a *prima facie* case of obviousness has not been established and respectfully request this rejection be withdrawn.

Claims 18-23, 26, 34, 35, and 42 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* in view of Seki (USPN 4,961,817).

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Claims 18, 23 and 26 are directed to a system, a device, and a kit (respectively) for delivering an orthopedic cement to a target bone site. An element of the claims is a pneumatic vibratory element. Claims 34, 35 and 42 additionally recite the limitation of a vibratory element, e.g., a pneumatic vibratory element.

Constantz et al., is directed to a system for both mixing and administering calcium phosphate cements. Seki is directed to a thin-film releasing technique for releasing a thin film stuck on a substrate and for drawing off the released thin film.

As stated above, the field of the Applicants' endeavor is the delivery of orthopedic cements and the particular problem the Applicants are concerned with is the controlled delivery of orthopedic cement to a target bone site without the substantial application of pressure. Seki, however, is directed to the production of thin films on a substrate and their subsequent release once they are produced. Accordingly, because Seki is not directed to the delivery of orthopedic cements to a target bone site, it is not in the Applicants' field of endeavor.

Accordingly, Seki is not concerned with the controlled delivery of cement (i.e., orthopedic cement) without the substantial application of pressure. Therefore, Seki represents non-analogous art because it is neither in the Applicant's field of endeavor nor is it reasonably pertinent to the problem with which the Applicant was concerned. Accordingly, one of reasonable skill in the art would not look to Seki for guidance as to the delivery of orthopedic cement to a target bone site. As such, the Applicants contend that a *prima facie* case of obviousness has not been established and respectfully request this rejection be withdrawn.

Claim 39 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Constantz *et al.* The Examiner asserts that Constantz discloses all

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the elements of the claimed invention except for the limitation that the amount of cement to be delivered is from about 4 to 10 cubic centimeters.

Claim 39 ultimately depends from independent Claim 36, which has been amended to include the limitation that the penetration of the cement into the bone stops substantially simultaneously with the cessation of vibration. Constantz neither teaches nor suggests the delivery of orthopedic cement by the use of vibration in a controlled manner **such that when the vibration stops the penetration of the cement stops substantially simultaneously with the cessation of vibration**. The reason that Constantz does not suggest this element is because Constantz et al. is completely silent as to whether penetration would cease at substantially the same time as removal of vibration. Because Constantz does not teach or suggest every element of the claimed invention it fails to render Claim 39 obvious.

The Examiner asserts that it would have been obvious to one of skill in the art to deliver about 4 to 10 cubic centimeters of cement. To support this conclusion the Examiner relies upon *In re Aller* for the proposition that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill. However, *In re Aller* does not apply to the present case.

In *In re Aller* the Applicant had claimed a process that was identical to the prior art in everyway except with respect to the recitation of the specific temperature and acid concentration to be used. See *In re Aller*, 42 C.C.P.A. 824, 827 (1955). This is different from the instant case because Claim 39 recites the limitation **that when the vibration stops the penetration of the cement stops substantially simultaneously with the cessation of vibration**. Constantz is completely silent as to this limitation. Accordingly, the present case is distinguishable from *In re Aller* in that the claimed process is not identical to that of the prior art.

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Furthermore, in *Aller* the only change in the process between the claim the prior art was with respect to temperature and reagent concentration. However, in the prior art there was an initial temperature and reagent concentration provided. Here, there is not prior art citation provided by the Examiner as to how much cement is introduced into vertebral bodies. **As such, the Examiner cannot assume pursuant to *Aller* that the claimed ranged is a mere optimization of the prior art range, as no prior art range has been provided.** Accordingly, *In re Aller* cannot be relied upon to render Claim 39 obvious.

In view of the above, the Applicants respectfully request the §103 (a) rejection of Claim 39 be withdrawn.

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CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SKEL-012.

Respectfully submitted,
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